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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/441,313 | 11/16/1999 | ALLAN SVENDSEN | 5709.200-US | 4161 |

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| EXAMINER | |
|---|---|
| HUTSON, RICHARD G | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1652 | |

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Advisory Action | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/441,313 | SVENDSEN ET AL. | |
| | Examiner | Art Unit | |
| | Richard G Hutson | 1652 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 07 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *07 June 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *62-78*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit: 1652

Continuation of 2. NOTE: Applicants proposed cancellation of claims 1-78 and the addition of new claims 79-90 raises new issues for consideration. Specifically applicants proposed amendment of claims, such as new claim 82 which specifies the alteration is Y358F, respectively, while the claim depends from new claim 79 which recites that the alteration is at position 356. Thus claims 82 appears to be indefinite in that it is unclear as to exactly what "alterations" the claimed variant must have..

Continuation of 5. does NOT place the application in condition for allowance because: With respect to the current rejection of claims 62-78 under 112 first paragraph based on a lack of enablement, the rejection remains for the reasons previously made of record.Applicants continue to argue that both the patent and scientific literature relating to alpha-amylases provides a wealth of information and guidance enabling the currently claimed genus of variants. Applicants arguments continue to be found not persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., encoding a variant alpha-amylase) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish:: (A) regions of the protein structure which may be modified without effecting alpha-amylase activity; (B) the general tolerance of alpha-amylases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of any alpha-amylase with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA sequence encoding any alpha-amylase, said alpha amylase having an amino acid sequence which is at least 70% identical to SEQ ID NO: 4 and having an alteration at a position corresponding to S356 or K376 The scope of the claims must bear a reasonable correlation with the scope of enablement (In r Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

With respect to the previous objection of the specification,as previously stated, applicants amendment of the specification, to overcome the previous rejection is acknowledged. It is further pointed out to applicants that while their amendment moves to overcome the previous objection it may still be considered somewhat confusing in the recitation "may also be separated as follows, i.e., meaning the same as the plus sign "Asp30Ala/Ser34Glu or N30A/S34E" as applicants have not maintained consistency with the first part of applicants amendment which recites "Ala30Asp + Glu34Ser or A3OD+E34S". Applicants attention is drawn to the actual mutations designated in each of the alternative means of indicating mutations. For simplicity in the illustration of the referred to inconsistencey, applciants attention is drawn t the first alteration only, which applicants recite as Ala30Asp or A30D versus Asp30Ala or N30A.